



UNITED STATES DEPARTMENT OF COMMERCE

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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO
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EXAMINER

ART UNIT	PAPER NUMBER
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7

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/504,741

Applicant(s)

CHEN, JUN

Examiner

Michael V. Meller

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED, 35 U.S.C. § 133.
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2001.
- 2a) ☐ This action is **FINAL** 2b) ☒ This action is non-final
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 2, 3, 8-10, 14-44 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-7, 11-13, and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f)
- a) ☐ All b) ☐ Some * c) ☐ None of.
- 1 ☐ Certified copies of the priority documents have been received.
- 2 ☐ Certified copies of the priority documents have been received in Application No. _____
- 3 ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17 2(a))
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e)

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I and the paste formulation of claim 45 as the elected composition in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the election of species is improper since it is not seen by applicant where the presence of a surfactant or a preservative would constitute an undue burden, that the restriction between Group I and Group VIV is improper, and that the search of the therapeutic agent would overlap with a biological method of using the agent. This is not found persuasive because applicant was required to enumerate all of the components of the elected paste formulation and as such required to pick between a colorant, stabilizer, surfactant or preservative which is done to establish one specific species for initial examination, genetic engineering can be used to make many different types of enzymes as well as their inhibitors, and the examiner has already established that even applicant has evidenced by virtue of their claims that many different uses exist for such paste formulations. Further, applicant is reminded of the extensive literature search involved which is quite extensive while not being co-extensive.

Claims 1, 4-7, 11-13 and 45 read on the elected invention. Claims 2, 3, 8-10, 14-44 and 46 were not elected by applicant, and are thus withdrawn from further consideration by the examiner.

It is not understood why applicant has elected oral administration since the examiner never required such an election.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

The attempt to incorporate subject matter into this application by reference to the US Patent applications: 09/346,905, 09/112,690, 09/15,277 and EP 99 402 482.6 is improper because the applications do not appear to be related to the instant application since the oath does not reflect their relationship nor does the instant specification. Applicant has directed the examiner to page 1 of the instant specification which makes reference to US applications, but this is only proper if the applications are related to the

instant application. If the applications are related to the instant application, then the specification and the oath need to be amended to reflect such. If the applications are not related, then the applications can be noted in the "Background of the Invention" if the applicant wants to include them to explain the background of the invention. Further, US Serial number 09/15,277 is non existant. The only application which may match this is 09/015,277 which is totally unrelated material to this invention. Thus, applicant is asked to check this information. Further, the use of an appendix at the end of the specification is improper as this is essential material which must be inserted into the body of the instant specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention

Claims 1, 4-7, 11-13 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite since the use of the term, "optionally" is confusing. Either the absorbant and the colorant are in the formulation or not. These can be claimed in dependent claims.

Claim 4 is confusing since the claims ends after "pump inhibitor" and then starts up again with letter (b). A claim is one sentence. Further, the markush group needs to end with "and" and not "or".

Claim 5 is not claiming a proper markush group.

Claims 6 and 7 are confusing since "Q.S. a carrier" is not understood. What is "Q.S. a carrier" referring to ? This is not art recognized.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-7, 11-13 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black et al. (see col. 24, line 55-col. 27, line 23, example 148), Belley et al. '576 (see col. 27, line 34-col. 30, line 17, example 148), or Belley et al. '343 (see col. 26, line 47-col. 30, line 26, example 148) taken with Synodis et al. (see abstract, the examples, col. 3, lines 45-50), Vermeer (see abstract, col. 17, lines 15-54, col. 20, lines 34-38, col. 29, lines 15-26, col. 31, lines 39-63, col. 36, lines 8-20), Baffelli et al. (see

abstract, col. 1, lines 1-20, 43-50, col. 2, lines 28-40, col. 4, lines 1-13, and col. 6, the table) and Norling et al. (see abstract, col. 2, lines 13-22, col. 10, lines 40-48, col. 11, lines 22-34).

Black and the Belley references each teach that 3-(cyclopropylmethoxy)-5,5-dimethyl-4-(4-methylsulfonyl)phenyl)-5H-furan-2-one is known to be used in a pharmaceutical formulation to treat COX-2 mediated diseases. The references do not teach to use specifically fumed silica, the specific colorant TiO_2 , specifically PEG 300, triacetin, and magnesium carbonate instead of calcium carbonate.

Synodis teaches that drugs can be formulated into a paste using triacetin, fumed silica, TiO_2 and PEG.

Vermeer teaches that personal products can be formulated using PEG, fumed silica, and TiO_2 .

Baffelli teaches that paste formulations can contain TiO_2 and fumed silica.

Norling teaches that a pharmaceutical formulation can be made which contains magnesium carbonate, PEG, and Triacetin.

It would have been obvious to one of ordinary skill in the art to use fumed silica in the formulations of Black and the Belley references since Synodis, Vermeer and Baffelli all teach that fumed silica is a well know ingredient in such formulations and is commonly used in such formulations as a thickening agent. Such a thickening agent would be desirable to use when making a paste which requires to be thick. To use the specific colorant TiO_2 would have been obvious since a colorant is taught by the primary references and this specific colorant is well known in the art to be used in such

formulations as taught by Synodis, Vermeer and Baffelli. To use PEG 300 specifically would have been the choice of the artisan since many forms of PEG are known as is evidenced by Synodis, Vermeer and Norling. To use triacetin also would have been obvious since Triacetin is well known in the art to be routinely used in such compositions as is evidenced by Synodis and Norling. To use magnesium carbonate instead of calcium carbonate as Black and the Belley references teach would also have been obvious since Norling teaches that magnesium carbonate is a well known alternative to calcium carbonate and it is well within the purview of the skilled artisan to use such substitutions in an effort to optimize the desired results of the claimed invention.

Further, to use the specifically claimed ranges of the ingredients that are not shown in the cited references would have been obvious since it is well within the purview of the skilled artisan to use such amounts in an effort to optimize the desired results of the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 10:30am-7:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

MVM
June 13, 2001

M. Wityshyn
JUN 14 2001
TRIAL EXAMINER
ART UNIT 1651